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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,537	02/07/2002	Brian Foley	MCA-483 PC/US	4091
25182	7590	09/30/2004	EXAMINER	
MILLIPORE CORPORATION 290 CONCORD ROAD BILLERICA, MA 01821			SODERQUIST, ARLEN	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,537

Applicant(s)

FOLEY, BRIAN

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 8-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2-7-02.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

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1. The disclosure is objected to because of the following informalities: an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., National Stage, continuation, divisional, or continuation-in-part) between the applications.

Appropriate correction is required.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. For examination of the apparatus claims (1-2 and 8-20), the perforated support is being treated as a support having two or more through holes therethrough.

4. Claims 1-2, 8-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jolley (US 4,704,255). In the patent Jolley teaches an assay cartridge having a substantially rectangular base plate, a substantially rectangular top plate, and four side walls. The top plate has a plurality of aligned adjacent reaction wells (through holes) located on its top side. Each well has a hole at its bottom opening into a waste reservoir, the space inside of the base plate, top plate and four walls. A filter membrane is positioned against the underside of the top plate covering the well holes. Column 3, lines 59-68 and column 7, lines 63-67 teach that the base plate, top plate and four side walls may be constructed of molded plastic such as acrylic, polystyrene, polycarbonate or other plastic material. The filter may have a pore size of about 10 microns or less for the purpose of retaining upon filtration a solid phase. The filter membrane may be constructed of cellulose acetate, nitrocellulose, polyvinylidene fluoride, polyvinyl chloride, teflon, polysulfone, polyester, polycarbonate, paper or glass fiber. Column 5, lines 63-65 teach that the preferred number of wells is 96. Column 6, lines 34-51 discuss the filter membrane (71) and teach it positioned against and joined to the underside (37) of the top plate (35) covering the well holes (40). The filter membrane thus forms a seal around the periphery of each well hole and becomes the floor of the assay wells (39). In the preferred embodiment the

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filter membrane is a single filter unit positioned against the entire portion of the underside of the top plate, but alternate embodiments are possible. Column 8, lines 34-50 teach the filter membrane joined to the top plate by placing the filter membrane into the mold prior to injecting and molding the plastic into the form of a top plate. Other methods of joining and or forming a seal are ultrasonic heating, using solvents or another source of heat.

5. Claims 1-2, 13 and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kiovsy (US 4,526,690). In the patent Kiovsy teaches a multiwell apparatus for the assay of microliter quantities of body fluids which prevents fluid loss by lateral migration or gravity flow through a microporous membrane or ultrafilter. Column 2, line 60 to column 5, line 27 teach the invention is an improvement in filtration apparatus having at least one reaction well (preferably 96) which contains a first microporous membrane having an antibody bound thereto and adapted for the separation, selection and retention of a complementary antigen to the bound antibody from fluids. Attached adjacent to the first microporous membrane is a porous hydrophobic fabric which is positioned either above or preferably below the first microporous membrane (to form an underdrain. This hydrophobic fabric prevents fluid loss by lateral migration or gravity flow through the membrane in the absence of a vacuum force but will still allow diffusion of gases into or out the interior of each well on the plate. It will be appreciated that the number of wells found in the filtration plate (12) are simply a matter of convenience for the investigator. The plate may contain as few as one well or as many wells as are functionally permissible given the actual dimensions of the plate. The filtration plate may be formed of any resilient and nonreactive material commonly available, the composition of choice being a matter of convenience or economics only. Each well (22) comprises an aperture (24, through hole) through the entire depth of the plate, the thickness of the plate determining the volume of fluid to be retained within the well. The diameter of the aperture will vary to meet the user's needs but typically will range from 3 to 25 millimeters in diameter. The first microporous membrane filter (26), is disposed across and sealed about the aperture in the plate such that the area across each well will serve as a filtering area (28). Methods of bonding the microporous membrane to the plate and sealing it about the perimeter of the aperture are well known in the art and were not described in detail. The composition and flow characteristics of the first microporous membrane forming the filtering area across each aperture is also a matter of choice. Cellulose acetate,

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polyamides and polyvinylidene fluoride microporous membranes or the like can be used for binding antibody thereto. Ultrafiltration media can be utilized in lieu of microporous membrane. The apparatus shown in figure 3 includes a hydrophobic fabric (30) disposed across and bonded adjacent to the filtering areas of the wells. Preferably, the hydrophobic fabric is bonded to the first membrane abutting the perimeter of the apertures such that a minute space (34) is created and maintained between the fabric and the filtering area. The fabric may be heat bondable with a paraffin film (32) or the like or adhesive can be utilized for bonding to the filtration means. A polypropylene web can be utilized to bond the membrane to fabric rather than film. The fabric may be formed of woven or a nonwoven materials and be composed any of hydrophobic polyester, polyolefin, polytetrafluoroethylene or other polymer.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 8, 10, 14, 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jolley as applied to claim 1 above or claims 8-12, 14, 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiovsky as applied to claim 1 above, and further in view of Pham (US 6,063,338). In the patents Jolley or Kiovsky do not teach the extent of the materials used, 384 wells, or multiple shapes and/or volumes of the wells.

In the patent Pham teaches multiwell plates and platforms for fluorescent measurements having a plate-like shape including a low fluorescence high transmittance layer (30), an assay site (40), and well walls (50). Column 7, lines 19-37 teach that multiwell plates can offer any

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number of wells in any well arrangement on any multi-well plate format or footprint. Typically, wells will be arranged in two dimensional linear arrays and usually have between about 96 and 864 wells. Larger numbers of wells or increased well density can also be easily accomplished in a variety of well shapes and forms of small dimension and volume. Other commonly used number of wells include 1536, 3456, and 9600. Well volumes typically vary from 500 nanoliters to over 200 microliters, depending on well depth and cross sectional area. Well volumes of 1, 2, 5, 10, 20, 50, 100, 200, and 500 microliters are commonly used. Wells can be made in any cross sectional shape (in plan view) including, square, round, and hexagonal and combinations thereof. Wells can be made in any cross sectional shape (in vertical view) including, shear vertical walls with flat or round bottoms, conical walls with flat or round bottoms and curved vertical walls with flat or round bottoms and combinations thereof.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the filter plates of Jolley or Kiovsky to include other materials for the plate and different numbers, shapes and/or volumes of the wells according to the teachings of Pham because of the recognition that multiwell plates can have a variety of shapes, volumes and materials as taught by Pham.

8. Claims 8-12, 14-18 and 20-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiovsky as applied to claim 1 above, and further in view of Mass (US 3,502,437), Terasaki (US 4,599,315), Ecker (US 5,925,732) and Williams (WO 98/45406). In the patent Kiovsky does not teach the extent of the materials used, 384 wells, or multiple shapes and/or volumes of the wells or the claimed method of manufacture.

In the patent Mass teaches an identification card (1, a sheet material) having formed therethrough openings (14-15) with a member (17) secured to the underside (16) thereof. The member is attached to the card such that a liquid tight seal exists between the card and the member. This forms a cavity (19) of a depth about the thickness of the card to receive predetermined amounts of liquids for testing.

In the patent Terasaki teaches a microdroplet test apparatus having a plurality of wells therein. Column 3, line 65 to column 4, line 1 teaches the test apparatus includes a tray (12) made from plastic or other relatively inert material having a plurality of microtest wells (16) that may be molded, machined, or otherwise formed in the tray.

In the patent Ecker teaches a chemical reaction apparatus. The description of figures 7A and 7B teaches the reaction support is present in subportions located within reaction wells, (62) on a shaped body, (60). The shaped body is any solid inert with respect to the chemical reactions to take place and capable of appropriate shaping, sterilizing, cleaning and the like as may be desired. Polymer, e.g. nylon or PTFE, glass, ceramic or metal are exemplary materials. The reaction wells, are preferably molded or machined into a surface of the shaped body, in any convenient manner, such as by milling. The reaction wells are preferably in fluid communication with a second surface of the shaped body, and are optionally but preferably adapted to funnel liquid from a larger portion of the well to a smaller or funnel portion. The funnel portions are preferably located to cooperate with collection wells, (46) of a collection plate (44) adapted to lie adjacent the shaped body distal from the reaction wells. Column 11, lines 11-35 teach the formation of high density microwell plates by drilling an opening in the bottom of individual wells.

In the published application Williams teaches a device with an assay surface having hydrophilic liquid-retaining zones (14) separated by hydrophobic land areas (13). Each zone can retain a microvolume of the sample. Figures 1-2 show variations of the device. Pages 14-16 discuss the device including a substrate (12) having the microvolume wells (liquid retaining zones). The substrate can be made of polymeric films or other appropriate materials. The polymers include polyethylene, polypropylene, polyimides, fluoropolymers polycarbonates, polyurethanes and polystyrenes. The wells can be formed by processes such as thermal embossing, cast embossing, laser drilling, etching with reactive materials, or lamination of a sheet of patterned material containing a plurality of small openings (perforated sheet) onto a film. The device can include any desired number of microvolume wells within the range of 10-10,000. The microvolume wells can be of a uniform size as shown in figure 1 or can have different sizes as shown in figure 2. In figure 2, the largest wells are capable of holding substantially more than 25 microliters. The wells of figure 2 also have different shapes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the filter plate of Kiovsky to include other materials for the plate and different numbers, shapes and/or volumes of the wells according to the teachings of Mass, Terasaki, Ecker and Williams because of the recognition that multiwell plates can have a variety

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of shapes, volumes and materials as taught by Mass, Terasaki, Ecker and Williams. It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce the filter plate of Kiovsky by a method as taught by Mass or Williams in which a sheet of material having holes therein is bonded to a sheet to create the wells because of the respective advantages of such a method and the recognition taught by Mass, Terasaki, Ecker and Williams that multiwell plates can be made by a variety of methods other than through molding.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-2 and 8-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,742,659.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are of a scope that encompasses the patented claims and one could not practice the patented invention without coming within the instant claims.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to multiwell plates.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose current telephone number is (571) 272-1265 as a result of the examiner moving to the new USPTO location. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

A general phone number for the organization to which this application is assigned is (571) 272-1700. The fax phone number to file official papers for this application or proceeding is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ARLEN SODERQUIST
PRIMARY EXAMINER

September 29, 2004

A handwritten signature in cursive script, reading "Arlen Soderquist". The signature is written in dark ink and is positioned below the printed name and title.